



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

AB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,602	02/11/2002	Baldomero M. Olivera	2314-249	1498

6449 7590 10/04/2004

ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

SCHNIZER, HOLLY G

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/072,602

**Applicant(s)**

OLIVERA ET AL.

**Examiner**

Holly Schnizer

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.  
4a) Of the above claim(s) 4,5,7-9 and 12-14 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3,10,11,15 and 16 is/are rejected.  
7) ☒ Claim(s) 6 and 17-24 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 09 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 08/19/03.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, SEQ ID NOs: 352 and 534 in the reply filed on July 9, 2004 is acknowledged. The traversal is on the ground(s) that while the various conotoxins are distinct, they do not require an undue search burden. Applicants argue that a particular class of conotoxins will share a conserved cysteine framework, disulfide bridging pattern and conserved molecular target and therefore would not require a serious search burden. This is not found persuasive because while the  $\alpha$ -conotoxins may share a general 3-dimensional structure and similar cysteine framework and disulfide bridging pattern, the sequences and biological function of the peptides are quite distinct such that the search for the individual peptides would not be coextensive. Applicants state that the individually required search for each sequence is only a result of the limitations in the programming of the search engines and that nothing prevents one skilled in the art from writing a program that would search the peptidic chemical genus as it presently exists for the more traditional chemical genus. This argument has been considered but is not deemed persuasive because the examiner is necessarily limited by the search tools at hand and to write a new computer program would be considered undue search burden. As stated in the previous Office Action, Tables 1-14, containing the sequences encompassed by the claims, contain 638 sequences, most of which have sequences completely unique to any other. Thus, a search of one sequence would not provide any information regarding patentability of another. In addition to this, the claims are even broader to encompass a wide variety of

Art Unit: 1653

derivatives of the peptide sequences of Tables 1-14. Thus, as Applicants agree, the peptides are patentably distinct, and for the reasons cited above and in the previous Office Action, an undue burden of search would be required in the examination of all of the peptides encompassed by the claims.

The examiner notes that an undue burden of search is not required derivatives based on the sequences of SEQ ID NOs: 352 and 534 (such as SEQ ID NO:353 wherein a couple of residues have been modified but the main sequence is still present).

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.148(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Status of the Claims***

Claims 1-24 are pending. Claims 4-5, 7-9, and 12-14 are withdrawn as being drawn to a non-elected invention. Claims 1-3, 6, 10-11, 15-24 have been considered to the extent that they relate to peptides of SEQ ID NOs: 352 and 534 in this Office Action.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 1, line 31). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,633,347 (the '347 patent).

The '347 patent teaches the isolation of  $\alpha$ -conotoxins including  $\alpha$ -conotoxin M<sub>II</sub> (see Example 7). While the sequences of the  $\alpha$ -conotoxins of the '347 patent are not identical to SEQ ID NOs: 352 or 534 of the present Claims, the peptides disclosed in the '347 patent including M<sub>II</sub> are considered "*derivatives*" of the claimed peptides since they are of similar length and would have the same tertiary structure.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 10, 11, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to peptides disclosed in the Specification and *any derivative of those peptides* including derivatives that have any number amino acid changes (for example see Claim 3 which indicates that a derivative can have amino acid substitutions). Thus, the claimed genus encompasses any peptide sequence or structure. The Specification does not provide any derivatives and does not teach to what extent one may change the primary structure and still allow the peptide to fold properly and have the function disclosed in the Specification. The Specification teaches many different peptide sequences however the peptides disclosed have vastly different sequences and length and functions. The Specification does not provide any correlation between sequence and tertiary structure or sequence and function and thus the Specification does not set forth the invention in terms of distinguishing identifying characteristics that would allow one of skill in the art to recognize a sequence that would have the same fold and function as the peptide of SEQ ID NO:352 or 534.

### ***Claim Objections***

Claims 1-3, 6, 10-11, 15, 18, and 20-23 are objected to because the claims recite non-elected subject matter.

Claims 1-3, 6, and 10-11 are objected to for reciting specific sequences contained in Tables, rather than using the sequence identifier, SEQ ID NO:.  
Appropriate correction is required.

Claims 17, 19, 22, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the elected limitations of the base claim and any intervening claims.

### ***Conclusions***

No claims are allowable. The peptides of SEQ ID NOs: 534, 352, and 353 appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

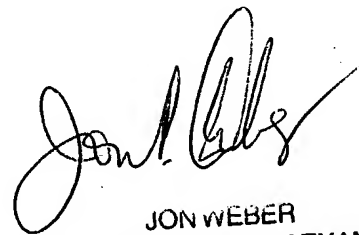
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Holly Schnizer  
September 28, 2004



JON WEBER  
SUPERVISORY PATENT EXAMINER